

Henson, Wanda

From: Sheryl Dolan <sdolan@actagroup.com>
Sent: Tuesday, August 04, 2015 11:04 AM
To: Fuller, Demson; Henson, Wanda
Subject: De Nora

Wanda and Demson:

Please advise if there is more that we need to do to resolve the product chemistry issues that Wanda and I discussed late yesterday. I reviewed the submission after we spoke and note the following:

- The preliminary analysis clearly covers five (5) batches of the salt; I have no explanation for why the chemist is only finding three.
- The data matrix should resolve the physical-chemical properties "gaps".
- We would like to review with you the requested changes to the CSF; as discussed, the chemist appeared to be confusing an "inert" with an "impurity", at least insofar as the chemist was asking for the supplier of the impurity.

As the PRIA date is the end of next week, we clearly wish to do all we can to resolve these issues expeditiously.

Thank you,

SHERYL LINDROS DOLAN

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